

PET FOOD INSTITUTE

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March 22, 2005

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 2004N-0264

Dear Sir or Madam:

On behalf of the members of the Pet Food Institute (PFI), the national trade association representing the companies that manufacture 97 percent of the dog and cat food sold in the United States, the following additional comments are offered to the above Docket Number. These comments specifically relate to the record keeping provisions.

Since the implementation of the 1997 rule to prevent the spread of BSE in the United States, PFI has heard complaints from its members and retailers that state inspectors have cited them for a perceived failure to keep records in the individual sales of pet food products to consumers. PFI believes the Agency never intended the record keeping requirements of the rule apply to retail sales of pet food and strongly believes the Agency should take this opportunity, while other changes to the rule are under consideration, to make an editorial clarification to expressly state that records are not required for individual retail sales of pet food.

PFI would propose the text in the following section of the rule be modified to expressly state the pet food sold through retailers, including veterinary clinics, feed stores and online, is not subject to the recordkeeping provisions. The specific section, 21 CFR §589.2000 (c) (4), currently reads as follows:

Pet food products that are sold or intended for sale at retail and feeds for nonruminant laboratory animals are exempt from the labeling requirements in paragraphs (c) and (d) of this section. However, if the pet food products or feed for nonruminant laboratory animals are sold or are intended for sale as distressed or salvage items, then such products shall be labeled in accordance with paragraph (c) or (d) of this section, as appropriate.

PFI believes the Agency never intended for the record keeping requirement to apply to direct-to-consumer sales of pet food for non-ruminant use. Therefore, PFI would request the Agency clarify the rule's coverage by adding the following text to 21 CFR §589.2000 (c)(4):

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There are no record-keeping requirements for products exempted from labeling. However, if the pet food products or feed for nonruminant laboratory animals are sold or are intended for sale as distressed or salvage items, then record-keeping requirements contained in paragraph (c) of this section shall be required.

The addition of this new language is appropriate given the Agency's ongoing review of the rule in light of the detection of BSE in the United States in December 2003. In addition, this new language is consistent with the view the Agency took in exempting pet food sold at retail from the labeling provisions of the rule. Specifically, in the preamble to the 1997 Final Rule, FDA stated:

FDA agrees that the cautionary statement serves no useful purpose on pet food and feed for nonruminant laboratory animals and has amended the rule by creating a new Sec. 589.2000(d)(4) to exclude pet food products that are sold or intended for sale at retail to non-food producing animals and feed for nonruminant laboratory animals. These products typically cost substantially more per ton than most complete feeds intended for food-producing animals. Therefore, there is little, if any, risk that pet foods or feeds for nonruminant laboratory animals will be purchased at full price for use in ruminant rations. (62 Federal Register 30955, 06/05/97) [emphasis added]

PFI would argue that any expectations that retailers should keep records on individual sales of pet food products to consumers also "serves no useful purpose" in the efforts to prevent the spread of BSE. On the contrary, it would only detract from the efforts needed to ensure compliance with other sections of this rule.

Sincerely,



Nancy K. Cook

Vice President, Regulatory & Technical Affairs

cc: Dr. Stephen Sundlof, Director, FDA Center for Veterinary Medicine
Dr. Rod Noel, Chair, AAFCO Pet Food Committee